IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

IRIS GALE MORTENSEN	§	
	§	
Plaintiff,	§	Civil No. _____
	§	
v.	§	
	§	
JOHNSON & JOHNSON INC., and ETHICON, INC.,	§	
	§	
	§	
Defendants.	§	

COMPLAINT AND JURY DEMAND

COMES NOW Plaintiff, IRIS GALE MORTENSEN ("Plaintiff"), by and through her attorneys of record, and files her Complaint and states as follows:

PARTIES

1. This action seeks to recover damages for the injuries sustained by IRIS GALE MORTENSEN ("Plaintiff") as the direct and proximate result of the wrongful conduct and negligence of the Defendants in connection with the design, development, manufacture, testing, packaging, promoting, marketing, advertising, distributing, labeling, and selling of GYNECARE TVT Exact Continence System manufactured by Ethicon, Inc., a subsidiary of Johnson & Johnson, implanted in the Plaintiff.

2. Defendant JOHNSON & JOHNSON ("J&J") is a corporation, and according to its website, the world's largest and most diverse medical device, and diagnostics company, with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Johnson & Johnson organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing, promotion, training, distribution,

and sale of its' pelvic floor repair products. Within the medical devices and diagnostic sector are "Business Units" including the "Ethicon Franchise." The Ethicon Franchise was charged by J&J with the design, development, promotion, marketing, testing, training, distribution, and sale of the pelvic floor repair products at issue in this case. The Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, Gary Pruden, is employed by J&J and include, but are not limited to, Ethicon Franchise are thus controlled by J&J and include, but are not limited to, Ethicon Inc., Ethicon LLC, Ethicon LTD.

3. Defendant, ETHICON, INC., is a wholly owned subsidiary of Defendant J&J located in Somerville, New Jersey.

4. At all times relevant herein, J&J and Ethicon, Inc., were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, testing, training, marketing, promoting, packaging, labeling, and/or selling such devices, including the GYNECARE TVT EXACT Continence System implanted in Plaintiff. At all times relevant hereto, and, upon information and belief, J&J, and Ethicon Inc., manufactured, marketed advertised, promoted, and sold the GYNECARE TVT EXACT Continence System worldwide.

5. Defendants J&J and Ethicon, Inc., (hereinafter referred to collectively as "Defendants") had a legal duty to ensure the safety and effectiveness of their pelvic mesh products by conducting adequate and well-controlled studies on their products prior to marketing. Defendants deliberately chose to manipulate the only studies that were conducted on their products and by so doing provided doctors and patients in the United States with accurate information regarding the lack of proof of the safety and effectiveness of their pelvic mesh products.

JURISDICTION AND VENUE

6. Federal subject matter jurisdiction in the constituent actions is based upon 28 U.S.C. § 1332(a), in that there is complete diversity among Plaintiff and Defendants and the amount in controversy exceeds $75,000.

7. Defendants have significant contacts with the United States District Court for the Southern District of Texas such that they are subject to the personal jurisdiction of the court in said district.

8. Plaintiff is a citizen and resident of Galveston County, State of Texas, and this division.

9. A substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in in the United States District Court for the Southern District of Texas. Pursuant to 28 U.S.C. § 1391(a), venue is proper in said district.

FACTUAL BACKGROUND

10. Surgical mesh products have been used to repair abdominal hernias since the 1950s. In the 1970s, gynecologists began using surgical mesh products designed for hernia repair for abdominal repair to surgically repair prolapsed organs. In the 1990s, gynecologists began using this surgical mesh for the surgical treatment of pelvic organ prolapse (POP") and stress urinary incontinence ("SUI"). Manufacturers, including Defendants, began to modify the mesh used in hernia repair to be used as products specifically intended to correct POP and SUI. Today, Defendants sell pelvic mesh "kits" which can include not only the surgical mesh, but also tissue fixation anchors and insertion tools. The GYNECARE TVT EXACT Continence System manufactured by Defendants (hereinafter referred to as the "Mesh Product") is considered Class II medical devices.

11. The Mesh Product is targeted for women who suffer from stress urinary incontinence as a result of the weakening or damage caused to the walls of the vagina. These products are specifically promoted to physicians and patients as an innovative, permanent, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma and minimal pain while permanently correcting vaginal prolapse, stress urinary incontinence, organ prolapse and/or rectocele.

12. Moreover, these Mesh Product contains polypropylene mesh. Despite claims that this material is inert, the scientific evidence shows that this mesh material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving the Mesh Product. This immune response promotes degradation of the polypropylene mesh, as well as the pelvic tissue, and can contribute to the formation of severe adverse reactions to the mesh.

13. At various times, Defendants sought and obtained Food and Drug Administration ("FDA") clearance to market the Mesh Product under Section 510(k) of the Medical Device Amendment. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. This clearance process did not require Defendants to prove the safety or efficacy of the Mesh Product and, thus, a formal review of the safety and efficacy of the Mesh Product was never conducted with regard to the Mesh Product.

14. At all times relevant hereto, the Mesh Product was marketed to the medical community, including Plaintiff's implanting physician, and directly to patients as safe, effective, permanent, reliable, medical devices; implanted by safe and effective, minimally invasive surgical

techniques for the treatment of medical conditions, primarily stress urinary incontinence, and as safer and more effective as compared to the traditional products and procedures for treatment.

15. Upon information and belief, the Defendants have consistently underreported and withheld information about the propensity of the Mesh Product to fail and cause injury and complications, and have misrepresented the efficacy and safety of the Mesh Product, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

16. Despite the chronic underreporting of adverse events associated with the Mesh Product, eventually enough complaints were recorded for the FDA to issue a public health notification regarding the dangers of these devices.

17. On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are not rare" (emphasis in the original).

18. The FDA Safety Communication also stated, "Mesh contraction (shrinkage) is a previously unidentified risk of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA . . . Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (emphasis in original).

19. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologist Society ("AUGS") also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating:

There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh. Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable

20. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

21. Plaintiff's type of injuries were reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion. 23. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks.

22. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

23. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologist Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the "White Paper"). In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh- related complications that are not experienced by patients who undergo traditional surgery without mesh."

24. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginal

placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk." (Emphasis in original).

25. The FDA White Paper further stated that "these products are associated with serious adverse events. Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non- mesh repair."

26. In its White Paper, the FDA advises doctors to, inter alia, "Recognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications."

27. The FDA concludes the White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

28. Defendants knew or should have known about the Mesh Product's risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

29. Defendants knew or should have known that the Mesh Product unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

30. Defendants had sole access to material facts concerning the defective nature of the Mesh Product and its propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the Mesh Product.

31. The scientific evidence shows that the material from which the Mesh Product are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Mesh Product, including Plaintiff.

32. This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by Plaintiff.

33. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an Issue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." The Mesh Product was unreasonably susceptible to degradation and fragmentation inside the body.

34. The Mesh Product was unreasonably susceptible to shrinkage and contraction inside the body.

35. The Mesh Product was unreasonably susceptible to "creep" or the gradual elongation and deformation when subject to prolonged tension inside the body.

36. At all times relevant hereto, the Mesh Product was marketed to the medical community and to patients, including Plaintiff and her implanting physician, as safe, effective, reliable, medical devices, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of stress urinary incontinence, and other competing products.

37. Defendants omitted the risks, dangers, defects, and disadvantages of the Mesh Product, and advertised, promoted, marketed, sold, and distributed the Mesh Product as a safe medical device when Defendants knew or should have known that the Mesh Product was not safe for its intended purposes, and that the Mesh Product would cause, and did cause, serious medical problems, and in some patients, including Plaintiff, catastrophic injuries.

38. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, the Mesh Product has high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff, making these products defective under the law.

39. The specific nature of the Mesh Product's defects includes, but are not limited to, the following:

a. the use of polypropylene material in the Mesh Product and the immune reactions that result from such material, causing adverse reactions and injuries.

b. the design of the Mesh Product to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries.

c. biomechanical issues with the design of the Mesh Product, including, but not limited to, the propensity of the Mesh Product to contract or shrink inside the body, that in turn causes surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury.

d. the use and design of arms and anchors in the Mesh Product, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region.

e. the propensity of the Mesh Product to "creep," or to gradually elongate and deform when subject to prolonged tension inside the body.

f. the inelasticity of the Mesh Product, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking).

g. the propensity of the Mesh Product for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time.

h. the hyper-inflammatory responses to polypropylene leading to problems including chronic pain and fibrotic reaction.

i. the adverse tissue reactions caused by the polypropylene products, which are causally related to infection, as the polypropylene is a foreign material to the human body.

j. the harshness of cross-linked polypropylene upon the female pelvic tissue, and the hardening of the product in the body.

k. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions.

40. The Mesh Product is also defective due to Defendants' failure to adequately warn or instruct Plaintiff and her implanting physician of subjects including, but not limited to, the following:

a. the Mesh Product’s propensities to contract, retract, and/or shrink inside the body.

b. the Mesh Product’s propensities for degradation, fragmentation and/or creep.

c. the Mesh Product's inelasticity preventing proper mating with the pelvic floor and vaginal region.

d. the rate and manner of mesh erosion or extrusion.

e. the risk of chronic inflammation resulting from the Mesh Product.

f. the risk of chronic infections resulting from the Mesh Product.

g. the risk of permanent vaginal or pelvic scarring as a result of the Mesh Product.

h. the risk of recurrent, intractable pelvic pain and other pain and other pain resulting from the Mesh Product.

i. the need for corrective or revision surgery to adjust or remove the Mesh Product.

j. the severity of complications that could arise as a result of implantation of the Mesh Product.

k. the hazards associated with the Mesh Product.

l. the Mesh Product's defects described herein.

m. treatment of stress urinary incontinence with the Mesh Product is no more effective than feasible available alternatives.

n. treatment of stress urinary incontinence with the Mesh Product exposes patients to greater risk than feasible available alternatives.

o. treatment of stress urinary incontinence with the Mesh Product makes future surgical repair more difficult than feasible available alternatives.

p. uses of the Mesh Product put the patient at greater risk of requiring additional surgery than feasible available alternatives.

q. removal of the Mesh Product due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. complete removal of the Mesh Product may not be possible and may not result in complete resolution of the complications, including pain.

41. Defendants have underreported information about the propensity of the Mesh Product to fail and cause injury and complications and have made unfounded representations regarding the efficacy and safety of the Mesh Product through various means and media.

42. Defendants failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Mesh Product.

43. Defendants failed to design and establish a safe, effective procedure for removal of the Mesh Product, or to determine if a safe, effective procedure for removal of the Mesh Product exists.

44. Feasible, safer, and suitable alternatives to the Mesh Product have existed at all times relevant, including at the time of manufacture, that do not present the same frequency or severity of risks as do the Mesh Product. Some of these feasible and suitable alternatives include but are not limited to:

a. The use of sutures, including delayed absorbable sutures like PDS, in colposuspension procedure like the Burch.

b. autologous facia sling.

c. an allograft sling such as Repliform; and

d. a sling with less polypropylene such as Ultrapro

e. corrective surgery without the use of mesh.

45. The Mesh Product was at all times utilized and implanted in a manner foreseeable to Defendants, as Defendants generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physician.

46. Defendants provided incomplete and insufficient training and information to physicians regarding the use of the Mesh Product and the aftercare of patients implanted with the Mesh Product.

47. The Mesh Product implanted in Plaintiff were in the same or substantially similar condition as they were when they left Defendants' possession, and in the condition directed by and expected by Defendants.

48. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Mesh Product include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain.

49. In many cases, including Plaintiff's, the women have been forced to undergo extensive medical treatment, including, but not limited to operations to located and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine and the vagina, and operations to remove portions of the female genitalia.

50. The medical and scientific literature studying the effects of Defendants' mesh products, like that of the Mesh Product implanted in Plaintiff, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the Mesh Product.

51. Removal of contracted, eroded and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

52. At all relevant times herein, Defendants continued to promote the Mesh Product as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy.

53. In doing so, Defendants failed to disclose to Plaintiff, Plaintiff's healthcare providers, and the medical community, the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Mesh Product.

54. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff, Plaintiff's implanting physician, and the medical community, on notice of the dangers and adverse effects caused by implantation of the Mesh Product.

55. Defendants had a duty to exercise reasonable and ordinary care in the recruitment and training of physicians to implant the Mesh Product.

56. The Mesh Product as designed, manufactured, distributed, sold and/or supplied by Defendants were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendants' knowledge of lack of safety.

57. Defendants knew that the Mesh Product, as designed, manufactured, distributed, sold and/or supplied by Defendants, were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing.

58. Defendants have intentionally and recklessly designed, marketed labeled, sold and distributed the Mesh Product with wanton and willful disregard for the rights and health of the

Plaintiff, and with malice, placing their economic interest above the health and safety of the Plaintiff and others.

59. Defendants' aforementioned acts and omissions constitute willful and or wanton conduct.

60. The Mesh Product, as designed, manufactured, distributed, sold and/or supplied by Defendants, was defective as marketed at the time they left Defendants' control.

61. On or about October 23, 2015, Plaintiff had the Mesh Product implanted at UTMB Health, in Galveston, Texas to treat her stress urinary incontinence.

62. Thereafter, Plaintiff began experiencing painful and serious complications, including but not limited to, constant and excruciating pain, urinary incontinence, fecal incontinence, and dyspareunia.

63. On or about July 10, 2019, Plaintiff underwent an operation at Pearland Medical Center, Pearland Texas, for the removal of the Mesh Product.

64. As a result of having the Mesh Product implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment, including procedures to correct her injuries, and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

Fraudulent Concealment

65. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through affirmative misrepresentations and omissions, actively concealed from Plaintiff, Plaintiff's physicians, the medical community, and the general

public the true risks associated with the Defendants' mesh products, including the Mesh Product implanted in Plaintiff.

66. As a result of Defendants' actions, Plaintiff, and her implanting physician were unaware, and could not reasonably have known or have learned through reasonable diligence, that they had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

COUNT I:
PRODUCT LIABILITY ACT – DESIGN DEFECT

67. Plaintiff hereby incorporates by reference all previous paragraphs and further states as follows:

68. Plaintiff is an expected user or consumer of the Mesh Products.

69. The Mesh Product implanted in Plaintiff was conveyed in a condition not contemplated by reasonable persons among those considered expected users of consumers of the Mesh Products.

70. Safer, feasible and suitable alternatives to the Mesh Product that were available to the Defendants have existed at the time of manufacture and conveyance that do not present the same frequency or severity of risks as does the Mesh Product. Safer and feasible alternatives include but are not limited to, human tissue slings, biological implants, native tissue repair, sutures, slings with less polypropylene, corrective surgery without implanted mesh, and pelvic floor therapy.

71. The burden of implementing safer, feasible, and alternative designs would not have outweighed the reduction of injury caused to consumers, including Plaintiff.

72. At the time of manufacture and conveyance, the Mesh Product failed to meet the minimum safety expectations of the ordinary user and consumer: Plaintiff expected that the

Mesh Product would treat and/or remedy her urinary incontinence without causing the aforementioned serious and painful complications.

73. The ordinary user and consumer would not consider the Mesh Product sufficiently safe given the aforementioned risks, dangers, and complications associated with the Mesh Product. The Mesh Product was dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

74. The aforementioned and foreseeable risks exceed and outweigh the benefit the Defendants purports the Mesh Product provides, that benefit being the treatment of stress urinary incontinence.

75. Defendants had a duty to individuals, including Plaintiff, to use reasonable care in designing, marketing, labeling, packaging, and selling the Mesh Product.

76. Defendants breached its duty to Plaintiff by failing to exercise due care under the circumstances.

77. Defendants knew or should have known Plaintiff could foreseeably suffer injury as a result of the defective design of the Mesh Product.

78. The defects in the Mesh Product implanted in Plaintiff existed from the time of manufacture and conveyance; therefore the defects were present when they left the possession and control of the Defendants.

79. The Mesh Product implanted in Plaintiff was, at the time conveyed, not in conformity with the generally recognized state of the art applicable to the safety of the Mesh Product at the time they were designed, manufactured, packaged, labeled, and/or sold.

80. The Mesh Product creates a risk to the health and safety of patients that are far more significant and devastating than the risks posed by other products and procedures available to

treat the corresponding medical condition, and which far outweigh the utility of the Mesh Product.

81. The Mesh Product was defective, unfit, unsafe and inherently dangerous for its intended and reasonably foreseeable uses. The Mesh Product was in said condition when it entered the stream of commerce and was received by Plaintiff. The Mesh Product does not meet or perform to the expectations of patients and their health care providers.

82. The Mesh Product used by Plaintiff's physician was not substantially changed, modified, or altered at any time in any manner whatsoever prior to use. The Mesh Product reached Plaintiff in such a condition that it was unreasonable dangerous to her. The Mesh Product was used in the manner for which it was intended, that is, for the treatment of stress urinary incontinence. This use resulted in injury to the Plaintiff.

83. The Mesh Product implanted in Plaintiff were not reasonably safe for its intended uses and were defective as described herein with respect to its design at the time it left Defendants' possession and control. As previously stated, the Mesh Product's design defects include, but are not limited to:

a. the use of polypropylene material in the Mesh Product and the immune reaction that results from such material, causing adverse reactions and injuries.

b. the design of the Mesh Product to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries.

c. biomechanical issues with the design of the Mesh Product, including, but not limited to, the propensity of the Mesh Product to contract or shrink inside the

body, that in turn causes surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury.

d. the use and design of arms and anchors in the Mesh Product, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region.

e. the propensity of the Mesh Product to "creep," or to gradually elongate and deform when subject to prolonged tension inside the body.

f. the inelasticity of the Mesh Product, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation).

g. the propensity of the Mesh Product for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time.

h. the hyper-inflammatory responses to polypropylene leading to problems including chronic pain and fibrotic reaction.

i. the adverse tissue reactions caused by the polypropylene products, which are causally related to infection, as the polypropylene is a foreign material to the human body.

j. the harshness of cross-linked polypropylene upon the female pelvic tissue, and the hardening of the product in the body; and

k. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

84. As a direct and proximate result of the Plaintiff being implanted with the Mesh Product's aforementioned defects as described herein, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment, including multiple procedures to correct her injuries and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including but not limited to obligations for medical services and expenses, and/or lost income and other damages.

85. As a direct and proximate result of Defendants' wrongful conduct as described herein, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment, including procedures to correct her injuries, and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

86. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct.

COUNT II
PRODUCT LIABILITY ACT – FAILURE TO WARN

87. Plaintiff hereby incorporates by reference all previous paragraphs and further states as follows:

88. The Mesh Product was defective by reason of failure of Defendants to provide adequate warnings or instructions.

89. Defendants knew or should have known Plaintiff could foreseeably suffer injury as a result of Defendant's failure to exercise ordinary care in providing adequate warnings as described herein.

90. Defendants knew that the Mesh Product implanted in Plaintiff as designed distributed, sold, and/or supplied by Defendants, was defective as marketed due to inadequate warnings, instruction, labeling and/or inadequate testing.

91. Absence of a warning or instruction renders the Mesh Product unreasonably dangerous for its intended use.

92. Defendants failed to properly and adequately warn and instruct the Plaintiff and her implanting physician as to the proper candidates, if any, and the safest and most effective methods of implantation and use of the Mesh Product.

93. Defendants failed to properly and adequately warn and instruct the Plaintiff and her implanting physician as to the risks and benefits of the Mesh Product given the Plaintiff's condition and need for information.

94. Defendants failed to properly and adequately warn and instruct the Plaintiff and her implanting physician with regard to the inadequate research and testing of the Mesh Product, and the complete lack of safe, effective procedure for removal of the Mesh Product.

95. The Mesh Product implanted in Plaintiff were not reasonable safe for their intended uses and were defective as described herein as a matter of law due to their lack of appropriate and necessary warnings. Specifically, Defendants failed to provide sufficient or adequate warnings to Plaintiff and her implanting physician regarding among other subjects:

a. the Mesh Product's propensities to contract, retract, and/or shrink inside the body.

b. the Mesh Product's propensities for degradation, fragmentation, disintegration and/or creep.

c. the Mesh Product's inelasticity preventing proper mating with the pelvic floor and vaginal region.

d. the rated and manner of mesh erosion or extrusion.

e. the risk of chronic inflammation resulting from the Mesh Product.

f. the risk of chronic infections resulting from the Mesh Product.

g. the risk of permanent vaginal or pelvic scarring as a result of the Mesh Product.

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Mesh Product.

i. the need for corrective or revision surgery to adjust or remove the Mesh Product.

j. the severity and frequency of complications that could arise as a result of implantation of the Mesh Product.

k. the hazards associated with the Mesh Product.

l. the Mesh Product's defects described herein.

m. treatment of stress urinary incontinence with the Mesh Product is no more effective than feasible available alternatives.

n. treatment of stress urinary incontinence with the Mesh Product exposes patients to greater risk than feasible available alternatives.

o. treatment of stress urinary incontinence with the Mesh Product makes future surgical repair more difficult than feasible available alternatives.

p. the use of the Mesh Product puts the patient at a greater risk of requiring additional surgery than feasible available alternatives.

q. removal of the Mesh Product due to complications may involve multiple surgeries and may significantly impair the patients' quality of life;

r. the nature, magnitude and frequency of complications that could arise as a result of implantation of the Mesh Product; and

s. complete removal of the Mesh Product may not be possible and may not result in complete resolution of the complications, including pain.

96. Defendants, by excising reasonable diligence, could have made such warnings available to Plaintiff, Plaintiff's healthcare providers, and the medical community.

97. As a direct and proximate result of Defendants' failure to provide Plaintiff, Plaintiff's healthcare providers, and the medical community with sufficient or adequate warnings, Plaintiff and Plaintiff's healthcare providers were not adequately informed of the potential dangers and/or defects of the Mesh Products.

98. Had Plaintiff's implanting physician had been adequately warned of the unreasonable dangers and risks of the Mesh Product, and the severity and likelihood of those dangers and risks, Plaintiff's physician would not have recommended the use of the Mesh Product in Plaintiff and/or recommended safer feasible alternatives, and Plaintiff's injuries could have being avoided.

99. Had Plaintiff's implanting physician been adequately warned of the aforementioned risks, complications, and dangers, Plaintiff's implanting physician would have informed Plaintiff of this information, and Plaintiff would not have consented to the implantation of the Mesh Product.

100. As a direct and proximate result of Defendants' failure to provide Plaintiff and Plaintiff's implanting physician with sufficient or adequate warnings, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment, including multiple procedures to correct her injuries, and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

101. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct.

COUNT III
NEGLIGENCE

102. Plaintiff hereby incorporates by reference and reavers each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

103. At all times relevant herein, Defendants had a duty to exercise reasonable and ordinary care in the development, design, label, packaging, instructions, warnings, sale, distribution, marketing, supply, advertisement, selling and other activities that are part and parcel of the sale and distribution of the Mesh Product, including a duty to ensure that the Mesh Product did not pose a significantly increased risk of bodily injury to its users.

104. Defendants had a duty to exercise reasonable care in the advertising and sale of the Mesh Product, including a duty to warn and instruct Plaintiff and other consumers, of the dangers associated with the use of the Mesh Product that were known or should have been known to Defendants at the time of the sale of the Mesh Product to the Plaintiff.

105. Defendants had a duty to exercise reasonable and ordinary care in the recruitment and training of physicians to implant the Mesh Product.

106. Defendants knew or should have known Plaintiff could foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

107. Defendants failed to warn the general public, including Plaintiff, of the risk of serious harm.

108. Defendants breached their duty to Plaintiff by failing to exercise due care under the circumstances.

109. Defendants failed to exercise ordinary and reasonable care in the development, design, manufacture, label, packaging, instructions, warnings, sale, distribution, marketing, supply, advertisement, selling and other activities that are part and parcel of the sale and distribution of the Mesh Product. Defendants were negligent in that they failed to provide adequate warnings and instructions to Plaintiff or to her implanting physician regarding the Mesh Product. Defendants further breached their duty of care in the recruitment and training of physicians to implant the Mesh Product.

110. Defendants were negligent in failing to use reasonable care as described herein in designing, marketing, labeling, packaging, and selling the Mesh Product. Defendants breached its aforementioned duty by:

a. Failing to design the Mesh Product so as to avoid an unreasonable risk of harm to women in whom the Mesh Product was implanted, including Plaintiff;

b. Failing to use reasonable care in the testing of the Mesh Product so as to avoid an unreasonable risk of harm to women in whom the Mesh Product was implanted, including Plaintiff;

c. Failing to use reasonable care in inspecting the Mesh Product so as to avoid an unreasonable risk of harm to women in whom the Mesh Product was implanted, including Plaintiff;

d. Failing to use reasonable care in the training and instruction to physicians for the safe use of the Mesh Product, including Plaintiff's implanting physician;

e. Failing to use reasonable care in studying the Mesh Product to evaluate its safety and to determine the nature, magnitude, and frequency of serious, life threatening complications that were known or knowable; and

f. Otherwise negligently or carelessly designing marketing, labeling, packageing and/or selling the Mesh Product.

111. The reasons that Defendants' negligence caused the Mesh Product implanted in Plaintiff to be unreasonably dangerous and defective in design include but are not limited to:

a. The use of polypropylene material in the Mesh Product and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of the Mesh Product to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Mesh Product, including, but not limited to, the propensity of the Mesh Product to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in the Mesh Product, which, when placed in the women, such as Plaintiff, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. The propensity of the Mesh Product for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. The inelasticity of the Mesh Product, causing it to be improperly mated to the delicate and sensitive areas of the pelvis where it is implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. The propensity of the Mesh Product for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. The hyper-inflammatory responses to polypropylene leading to problems including chronic pain and fibrotic reaction;

i. The propensity of the polypropylene products to degrade after implantation in the female pelvis, causing pain and other adverse reactions;

j. The adverse tissue reactions caused by the polypropylene products, which are causally related to infection, as the polypropylene is a foreign material to the human body;

k. The harshness of polypropylene upon the female pelvic tissue; and

l. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

112. Defendants also negligently failed to warn or instruct Plaintiff's implanting physician of subjects concerning the Mesh Product, including, but not limited to the following:

a. The Mesh Product's propensities to contract, retract, and/or shrink inside the body;

b. The Mesh Product's propensities for degradation, fragmentation and/or creep;

c. The Mesh Product's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Mesh Product;

f. The risk of chronic infections resulting from the Mesh Product;

g. The risk of permanent vaginal or pelvic scarring as a result of the Mesh Product;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from the Mesh Product;

i. The need for corrective or revision surgery to adjust or remove the Mesh Product;

j. The severity of complications that could arise as a result of implantation of the Mesh Product;

k. The hazards associated with the Mesh Product;

l. The Mesh Product's defects described herein;

m. Treatment of stress urinary incontinence with the Mesh Product is no more effective than feasible and practical available alternatives;

n. Treatment of stress urinary incontinence with the Mesh Product exposes patients to greater risk than feasible and practical available alternatives;

o. Treatment of stress urinary incontinence with the Mesh Product makes future surgical repair more difficult than feasible and practical available alternatives;

p. Use of the Mesh Product puts the patient at greater risk of requiring additional surgery than feasible and practical available alternatives;

q. Removal of the Mesh Product due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. Complete removal of the Mesh Product may not be possible and may not result in complete resolution of the complications, including pain.

113. As a direct and proximate result of having the Mesh Product implanted in her with the aforementioned defects, Plaintiff experienced the aforementioned painful and serious complications.

114. As a direct and proximate result of Defendants' negligent failure to provide Plaintiff and Plaintiff's implanting physician with sufficient or adequate warnings, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment, including procedures to correct her injuries, and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

115. As a direct and proximate result of Defendant's negligent conduct, including including Defendants' negligent design, labeling, marketing, sale and distribution of Mesh Product,

Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT IV – BREACH OF IMPLIED WARRANTY

116. Plaintiff hereby incorporates by reference and reavers each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows

117. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the good and became part of the basis of the bargain creating an implied warranty that the good shall conform to the affirmations of fact or promises.

118. At the time of making such implied warranties, Defendants knew or should have know that the Mesh Product does not conform to these representations because the Mesh Product were not safe and have numerous side effects, many of which Defendants did not accurately warn about, thus making the Mesh Product unreasonably unsafe for their intended purpose.

119. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff and her implanting physician, relied upon the representations and warranties of Defendants in connection with the use recommendation, description, and/or dispensing of the Mesh Product.

120. Plaintiff and Plaintiff's implanting physician, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

121. Defendants were made aware of the breach through previously filed lawsuits regarding the Mesh Product.

122. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted and sold the Mesh Product.

123. At all relevant times, Defendants intended that the Mesh Product be implanted for the purposes and in the manner that Plaintiff or Plaintiff's implanting physicians in fact used them and Defendants impliedly warranted each product to be of merchantable quality, safe and fit for such use, and was not adequately tested.

124. At all relevant and material times, Defendants developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities that are part and parcel of the sale and distribution of its product, the Mesh Product, representing the quality and effectiveness to health care professionals, the FDA, Plaintiff and Plaintiff's implanting physician in such a way as to induce its purchase or use, thereby making an express warranty that the Mesh Product would conform to the representations. More specifically, Defendants represented that the Mesh Product was safe and effective, that it was safe and effective permanent implant for use by individuals such as Plaintiff, and/or that it was safe and effective to treat Plaintiff's conditions.

125. Defendants were aware that consumers, including Plaintiff and/or Plaintiff's physicians, would implant the Mesh Product in the manner directed by the instructions for use; which is to say that Plaintiff was a foreseeable user of the Mesh Product.

126. Plaintiff and/or her physicians were at all relevant times in privity with Defendants.

127. The Mesh Product was expected to reach and did in fact reach consumers, including Plaintiff or Plaintiff's physicians, without substantial change in the condition in which they manufactured and sold the Mesh Product.

128. Defendants breached various implied warranties with respect to the Mesh Product, including the following particulars.

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters and regulatory submissions that the Mesh Product was safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the Mesh Product;

b. Defendants represented that the Mesh Product was safe, and/or safer than other alternative devices or procedures and fraudulently concealed information, which demonstrated that the Mesh Product was not as safe or safer than alternatives available on the market; and

c. Defendants represented that the Mesh Product was more efficacious than other alternative medications and fraudulently concealed information regarding the true efficacy.

d. Defendants represented that the Mesh Product would treat and/or correct the Plaintiff's urinary incontinence.

129. In reliance upon Defendants' implied warranty, Plaintiff used the Mesh Product as prescribed and in the foreseeable manner normally intended, recommended, promoted and marketed by Defendants.

130. Defendants breached their implied warranty to Plaintiff in that the Mesh Product was not of merchantable quality, safe and fit for its intended use, or adequately tested, in violation of Common Law principles.

131. The Mesh Product implanted in Plaintiff failed to function as intended and as represented by Defendants because they did not relieve the symptoms or otherwise alleviate the medical condition they were intended to permanently treat and/or cure; that being Plaintiff's urinary incontinence. Instead, the Mesh Product contained the aforementioned defects that caused Plaintiff to suffer dyspareunia, urinary incontinence; fecal incontinence; and constant, excruciating pain; and other severe adverse health consequences. Because the Mesh Product failed to conform to representations and were not suitable for the purpose for which they were used, Defendants have breached their implied warranties.

132. As a direct and proximate result of Defendants' wrongful conduct, including Defendants' breach of implied warranty, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

WHEREFORE, Plaintiff demands a trial by jury, judgment against Defendants for compensatory and punitive damages in an amount exceeding $75,000, as well as, interest, or any other relief, monetary or equitable, to which they are entitled.

PLAINTIFF DEMANDS A TRIAL BY JURY

Dated May 20, 2021

Respectfully submitted,

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